AUG 3 1 2001

K011427

Premarket Notification 510(k) Summary

Mills Biopharmaceuticals, Inc.
120 N.E. 26th Street
Oklahoma City, Oklahoma 73104
Phone 405-525-3141
Fax 405-525-3143
Contact Person: Stanley L. Mills, Ph.D.
Date of Summary Preparation: 30 April 2001

Device Classification Name:	SOURCE, BRACHYTHERAPY, RADIONUCLIDE
Trade Name:	MBI Pd103 Brachytherapy Seed
Common Name:	Pd-103 Brachytherapy Seed
Equivalence:	I-125 Seeds by MBI and Theragenics Model 200
Description:	Palladium-103 Sources 4.5 mm x 0.8 mm nominal. The cylindrical metal casing is titanium having a wall thickness of 0.05 mm nominal laser welded at both ends. Model Pd-103SL and Pd-103SH- Palladium-103 coated five silver spheres.
Technological Characteristics:	Model Pd-103 brachytherapy sources are encapsulated with titanium and sealed by welding the ends closed. The multiple silver balls in the model Pd-103 provides improved radiographic visualization over resin and gold balls or graphite and lead pellets in similar designs. Radiographic visualization post implantation is different from our design in the composition of the interior balls. For Pd-103 products: Pd-103 is adsorbed onto silver balls which also provide radiographic visualization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2001

Stanley L. Mills, Ph.D., R.Ph.
President and CEO
MILLS BIOPHARMACEUTICALS INC.
120 N.E. 26th Street
OKLAHOMA CITY OKLAHOMA 73105

Re: K011427
MBI Pd-103 Brachytherapy Seed
(Pd.-103 Brachytherapy Seed)
Dated: July 17, 2001
Received: July 24, 2001
Regulatory Class: II
21 CFR 892.5730/Procode: 90 KXK

Dear Dr. Mills:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4,xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Appendix 2

510(k) Number (if known): K011427
Device Name: Pd-103 Brachytherapy Seed

INDICATIONS FOR USE:

Pd-103 SL brachytherapy seeds with apparent activities between 3.7 MBq (0.1 mCi) to78 MBq (2.11 mCi) are indicated for permanent interstitial treatment of tumors which are unresectable or residual after excision of the primary lesion, localized, slow growing, and low to moderate radiosensitivity. Intra abdominal, intrathoracic and superficial tumors may be treated with seeds containing apparent activities within this range. Tumors commonly treated are prostate (early stage), pancreas, head, neck, and lung.

Pd-103 SH brachytherapy seeds containing apparent activities greater than 78 MBq (2.11 mCi) are indicated for temporary interstitial treatment of tumors which are unresectable or residual after excision of the primary lesion, localized, with moderate radiosensitivity. Temporary implants are indicated in breast, brain and eye tumors.

Pd-103 brachytherapy seeds are indicated for treatment of residual tumors and recurrent tumors following external radiation therapy, hyperthermia, or chemotherapy or concurrent with these treatment modalities.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **Over-The-Counter Use**_____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K011427